

# Publicly available information for ISO/IEC 17065 – product conformity certification

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## 1. Types of certification schemes

CCQS Certification Services is a Notified Body, accredited by The Irish National Accreditation Board to ISO/IEC 17065:2012 (accreditation number 6028), to provide product conformity certification to the following Directives and Regulations:

### **PPE - The Personal Protective Equipment Regulation, (EU) 2016/425**

CCQS Certification Services has been notified to the Personal Protective Equipment Regulation (EU) 2016/425 (Notified Body number 2834)

Covering the following aspects:

Module B: EU type-examination

Module C2: Supervised product checks at random intervals

Module D: Quality assurance of the production process

### **Machinery Directive 2006/42/EC**

CCQS has been notified to Machinery Directive – 2006/42/EC Annex IX, EC Type Examination Certificate.

Details of CCQS's scope for each scheme can be found on the INAB Website available from:

<https://www.inab.ie/Directory-of-Accredited-Bodies/Certification-Bodies/Product-Certification/>

## 2. Initial Certification

Product certification is granted when CCQS concludes that:

- the product and any relevant documentation complies with the requirements of the legislation
- the requirements of any specified Harmonised Standard, Technical Specification or International Instrument are met
- any relevant approved guidance is complied with



Certification of products manufactured is granted when CCQS concludes that:

- the product has been selected by CCQS or its representatives successfully
- the selected product meets the requirements of the legislation
- any specified Harmonised Standard, Technical Specification or International Instrument are met
- any relevant approved guidance is complied with
- the selected product matches the original approved model or type
- and for Machinery Directive products that the product was satisfactorily inspected and safe functionality was witnessed.

Certification of the client's system for controlling the production or product is granted when CCQS concludes that:

- if relevant, the performance of the product has been established by CCQS based on type-testing
- the production and other relevant sites have been successfully audited by CCQS
- the manufacturer's factory production control system ensures conformity of the manufactured product with the declared performance or approved model
- any nonconformities are cleared to CCQS's satisfaction

#### **Certificate validity**

- Annex IV EC Type Examination certificates are issued with a validity of a maximum of 5 years.
- PPE Module B Certificates are issued with a validity of a maximum of 5 years.
- PPE Module C2 approval reports are issued with a validity of 1 year.
- PPE Module D Certificates are issued with a validity of 3 years.

### **3. Refusing Certification**

The decision to refuse certification is made by CCQS Certification Management.

For product certification and product selection and testing, this may occur when:

- the product does not meet the requirements of the legislation or the relevant standards and specifications
- the product no longer conforms with the original approved model
- the specified technical documentation does not meet the requirements of the legislation or the relevant standards and specifications

For factory production control systems, this may occur when:

- CCQS concludes that the quality system cannot ensure that the production conforms with the approved or declared model

### **4. Maintenance of Certification**

For any major nonconformity or other situation that may lead to suspension or withdrawal of certification, CCQS Certification Management will determine whether certification can be maintained.

#### **For product certification**

Product certification is maintained while the client complies with the conditions of certification:

- The address of the client is that which appears on the certificate
- The certificate has not been transferred or assigned to another organisation



- The certificate has not been lost, duplicated or altered without the authorisation of CCQS
  - The client is not promoting certification for products or services other than those covered by the certificate
  - The client is not claiming compliance with other standards through the use of the certificate or audit report other than that appearing on the certificate
  - Certificates or promotional materials associated with them do not contain misleading information
  - The client must investigate complaints associated with the certified products. Records of such complaints, and actions taken, must be kept by the client and made available to CCQS when requested
  - Production is limited to the site(s) notified to CCQS at the time of certification
  - Any change to the product or quality manual / quality plan shall be immediately notified to CCQS
- Renewal of product certification must be requested by the manufacturer before the Certificate expires. If required, declarations and relevant retesting must be submitted.

For factory production control systems Surveillance activities include on-site auditing of the client's management system.

Surveillance audits are on-site audits, but are not usually full system audits.

Certification is maintained provided that the client complies with the conditions of certification:

- The address of the client is that which appears on the certificate
- The certificate has not been transferred or assigned to another organisation
- The certificate has not been lost, duplicated or altered without the authorisation of CCQS
- The client is not promoting certification for products or services other than those covered by the certificate
- The client is not claiming compliance with other standards through the use of the certificate or audit report other than that appearing on the certificate
- Certificates or promotional materials associated with them are not promoting erroneous or misleading information
- The client must permit ongoing surveillance and access to documentation and records, and access to the relevant equipment, location(s), area(s), personnel and clients subcontractors
- The client must investigate complaints associated with the certified products or services. Records of such complaints, and actions taken, must be kept by the client and made available to CCQS when requested
- The client must allow participation of observers during surveillance audits when requested

For factory production control certificates with an expiry date, a re-assessment of the system must be completed by CCQS before the certificate can be re-issued. This re-assessment audit will normally be conducted at least 3 months before the certificate expiry date to allow for closure of any corrective actions and the reissue of the certification.

## 5. Suspension of Certification

Suspension of certification occurs when CCQS believes that:

- the product no longer meets the requirements of the legislation or relevant standards and specifications
- misuse of the certification has seriously breached the conditions of certification
- the clients quality system has persistently failed to meet certification requirements
- the client has not enabled surveillance audits or recertification audits to be conducted at the



prescribed intervals

- the certified client has requested the suspension of a certification
- there is a dispute over certificate ownership The client will be required to:
- Cease promoting their certification on advertising material
- Submit corrective action, if appropriate
- If relevant, allow access to CCQS's audit team to conduct an investigatory audit, if this is deemed appropriate, prior to lifting the suspension

Suspension is limited to a maximum period of 6 months before certification withdrawal commences. If certification is suspended, the client's certification is temporarily invalid:

- Certified product must not be sold or released.
- The client must discontinue its use of all advertising matter that contains any reference to the certification.

CCQS will restore the suspended certification if the issue that has resulted in the suspension has been resolved.

Where evidence is submitted or audits performed, CCQS Certification Management will determine whether certification can be reinstated, or whether the scope of certification or product performance or classification should be limited or reduced, or certification should be withdrawn.

## **6. Withdrawing Certification**

CCQS may withdraw certificates in the following cases:

- The client informs CCQS in writing that the certification is no longer required, or that they do not wish to maintain the validity of the Certificate;
- Wind-up of the client without a legal successor;
- Unauthorised use of the Certificate;
- The client is in breach of the certification agreement;
- The product no longer conforms to the original approved model;
- Production has been moved to a different production site without the approval of CCQS;
- The client does not accept scheduled surveillance or re-assessment audits; • A serious non-conformity reoccurs in two consecutive audits;
- Non-conformities raised in the audits are not corrected within the time limit prescribed by CCQS;
- The maximum period of a suspension has ended and corrective actions required were not carried out

Complaints can also result in certification withdrawal and will be judged by CCQS Certification Management on a case by case basis.

Upon withdrawal of certification, the client must discontinue its use of all advertising matter that contains any reference to the certification.

## **7. Expanding the scope of Certification**

A client wishing to expand the scope of certification must submit an application with details of the requested extension. CCQS will review the application and any submitted documentation. An additional audit may be necessary, or it may be combined with a surveillance audit. Additional product tests may be necessary.

## **8. Reducing the scope of Certification**



The scope of certification may be reduced in the following circumstances:

- At the client's request
- Following suspension of the certification
- If the client has persistently or seriously failed to meet the requirements for those parts of the scope
- If the product no longer meets the declared or tested performance or classification

## **9. CCQS's fees and status**

CCQS is an independent testing and certification organisation, owned by its management and staff. Fees are charged for all certification work. CCQS Certification Services is a wholly owned independent subsidiary of CCQS UK Ltd.

## **10. Rights and duties of applicants and clients**

For certification of products, the applicant must not have submitted the same product for certification to any other Notified Bodies.

For certification of product and production quality control systems for specific products, the applicant must not have applied to another Notified Body for approval of the system for those products.

### **PPE Module B and Annex IV Machinery Directive**

Clients must place CCQS's name, notified body number and address on the user information for any certified product. Clients must include CCQS's name, notified body number and address on their Declaration of Conformity.

### **PPE Module C2 and D**

Clients must place CCQS's notified body number on the PPE, beside the CE mark, for PPE manufactured during the validity of the certification.

Clients must place CCQS's name, notified body number and address on the user information for any certified product.

Clients must include CCQS's name, notified body number and address on their Declaration of Conformity.

## **11. The use of CCQS's name and certification mark and notified body numbers**

Information and requirements for the use of CCQS's name and certification mark is given to each certified client. Copies of this document can be supplied on request to certified clients.

### **General rules**

- The client must only make claims consistent with the scope of certification,
- The client must not make any misleading or unauthorised comments regarding the certified product or the certification body.
- The client must upon suspension, withdrawal, or termination of certification discontinue the use of all advertising matter that contains any reference thereto and take action to return this certificate to CCQS.

### **Use of the Notified Body Number**



The Notified Body Number must only be used:

- In direct association with products or systems covered by the certification.
- by holder(s) of the certification.
- Use of CCQS's Notified Body Number does not extend to other companies which are:
  - part of the same corporate group as the Certificate holding company: or
  - named in a Certificate, for example as a supplier.

- Particular care must always be taken to avoid the association of the CCQS Notified Body Number with other products or systems or schemes and with claims or information not contained in the CCQS document.

### **Personal Protective Equipment Regulation**

The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No 765/2008, followed by the number of the notified body when associated with production control monitoring (Module C2/D).

### **12. Procedures for complaints and appeals Complaints**

A complaint is any formal expression of dissatisfaction raised with CCQS in regard to its certification activities, its clients, or its services to clients.

All such complaints will be processed using CCQS's procedure for complaints management. If the complaint is not in writing, confirmation will be requested. Complaints will be acknowledged in writing, and investigated. The complainant will be advised of the outcome of the investigation. Complainants have the right of appeal, when a complaint is not resolved to the satisfaction of the complainant.

CCQS will determine, together with the complainant and the certified client, whether and, if so to what extent, the subject of the complaint and its resolution is made public.

### **Appeals**

An appeal is a formal review process when a client disagrees with a certification decision made by CCQS, either to certify or not to certify.

Appeals must be received within 6 weeks of the complainant being advised of the outcome of the investigation into their complaint. If the appeal is not in writing, confirmation will be requested. One of CCQS's Certification Management will review the appeal. If it is rejected, the appellant will be informed of the reasons.

If the appeal is rejected, the complainant may seek a further appeal. An Appeals Panel will be appointed, including CCQS's Managing Director and a representative from CCQS's Certification Management, which will review the appeal. Representatives from CCQS, technical experts, and the appellant will be invited to attend, as deemed necessary. The Appeals Panel will make a decision and set out any appropriate corrective action.

### **13. Requests for information**

CCQS will provide, upon request, information about:

- The geographical areas in which it operates;
- The status of a given certification;
- The name, standard, scope and geographical location (city and country) for a specific certified client. Requests should be made to CCQS using the contact details listed above.

### **14. Information provided to third parties**

The Directives and Regulations for which CCQS is notified impose requirements on Notified Bodies



for the provision of, or access to, information regarding their certification activities, and the results and conclusions of those activities.

### **Personal Protective Equipment Regulation and Machinery Directive**

Any technical documentation and certification may be accessed by the Irish competent authority, i.e. DBEI (Department of Business, Enterprise and Innovation)

CCQS will inform DBEI of any certificates or quality system approvals issued or extended, and any refusal, restriction, suspension or withdrawal of a certificate (Module B) or approval decision (Module C2 or D).

CCQS will inform other notified bodies of any EU type-examination certificates and extensions or quality system approvals which it has refused, withdrawn, suspended or otherwise restricted, and will provide notified bodies carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to negative conformity assessment results.

On request, CCQS will provide other notified bodies with information of EU type-examination certificates and extensions or quality system approvals which it has issued, and will provide notified bodies carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to relating to positive conformity assessment results.

On request, the European Commission, other PPE notified bodies and the other EU Member States may obtain a copy of EU type-examination certificates.

Following a reasoned request, CCQS may provide the European Commission, other PPE notified bodies and the other EU Member States with a copy of the technical file and the reports of the examinations and tests conducted.

